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| EXAMINER | |
|---|---|
| PAGE, BRENT T | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/573,885 | ONO ET AL. | |
| | Examiner | Art Unit | |
| | BRENT PAGE | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *6,8-10 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I in the reply filed on 10/16/2009 is acknowledged. The traversal is on the ground(s) that the technical feature linking the inventions is not a piperitol or sesamin but rather a protein that catalyzes the biosynthesis of piperitol or sesamin and therefore Ozaki et al does not disclose the special technical feature. This is not found persuasive because one of the inventions is a gene that encodes a protein, and a method of using the gene. It is possible to use this gene in altering levels of piperitol or sesamin that do not involve the protein whatsoever. Additionally, the preparation of an antibody that recognizes said protein has no relation to the gene sequence. Therefore, because gene and protein remain un-named and the breadth of the claims allow for them to be different between inventions, the only claim limitations linking the inventions is the recitation of piperitol and sesamin.

If, in the process of searching, the polypeptide of the instant invention is searched and found to be free of the art, rejoinder will be considered for claims directed to the polypeptide.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 are pending. Claims 6, 8-10, and 21 are withdrawn as being drawn to non-elected subject matter.

Claims 1-5, 7, and 11-20 are examined herein upon the merits.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are two embedded hyperlinks in the published specification in paragraph 22 and paragraph 237. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 101***

Claims 1-5, 7, and 12-14, 16 and 18 are rejected under 35 U.S.C. 101 because the claims are drawn to non-statutory subject matter.

Claims 1-5, and 7 all recite "a gene encoding a protein". The claims do not limit such genes to ---isolated--- genes, and therefore the "Hand of Man" has not been demonstrated. The claims drawn to "a gene" are therefore indistinguishable from products of nature and thus, drawn to non-statutory subject matter. It is suggested that Applicant amend the claims to indicate that the gene has been isolated. Care should be taken to avoid introducing New Matter into the claims.

Claims 12-14, 16 and 18 are all drawn to "a transformant", or a method of producing "a transformant". However, the term "transformant" encompasses any host including humans. On page 28 of the specification mentions that the host may be animal or plant and that animal cell lines from "mice, hamsters, monkeys or human" may be used. The claims are therefore drawn to non-statutory subject matter. It is suggested that Applicants amend the claims to indicate that humans are not

encompassed by the claims. Care should be taken to avoid introducing New Matter into the claims.

***Claim Rejections - 35 USC § 112&101***

Claims 15-20 provides for the "use of a gene according to claim 1", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 5, 7, and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to any gene encoding any enzyme that catalyzes the biosynthesis of piperitol or sesamin, wherein the resulting amino acid sequence has any number of unspecified substitutions, deletions, insertions or additions, wherein the amino acid sequence has as little as 50% identity to SEQ ID NO:1, transformants comprising said genes and methods of using said genes, as well as any genes comprising "a base sequence" from SEQ ID NO:2.

In contrast, the specification only describes 3 full-length p450 homologues from the CYP81 family which show at least 86% sequence homology to one another at the amino acid level. The specification also only describes the transformation of tobacco plants with the full length p450 homologue from Sesamum inidcum, and an increase in sesamin in the transformed plant. The specification does not describe any other variants other than the 3 full-length homologues that encode a protein that catalyzes the synthesis of piperitol or sesamin, nor does the specification describe the transformation of any species other than plant species with said genes. The claims encompass multitudes of nucleic acid and amino acid sequences wherein the genes and resultant proteins could have any activity so long as they catalyze the biosynthesis of piperitol or sesamin. While three examples are described and demonstrated, these examples are limited to the CYP81 family of the p450 super family, even though 13 such families were represented in the probes to look for such genes encoding enzymes. Therefore, the

specification does not describe a representative number of examples given the extremely large genus encompassed by the claims as currently written.

In the absence of a representative number of working examples, Applicant is required to describe the structures required for the claimed function. In the instant claims, the claimed function is catalyzing the synthesis of piperitol or sesamin. The specification does not disclose the nucleotide or the amino acid sequences that are required for the enzymes that would catalyze the synthesis of piperitol or sesamin. Sequences that encode amino acid sequences with as little as 50% identity to SEQ ID NO:1 could have anywhere from 1 to 253 amino acids substituted, deleted, or inserted in any combination along any length of SEQ ID NO:1. Furthermore, this reads on nucleic acid sequences with as little as 33.3% sequence identity to SEQ ID NO:2 when taking into account the degeneracy of the code and reads on anywhere from 1 to 1177 nucleotide substitutions, deletions or additions relative to SEQ ID NO:2. With no description of the required sequences that may not be altered in order to retain the function of a protein that catalyzes the biosynthesis of piperitol or sesamin, and without a representative number of working examples, the claims as currently written lack description over the entire breadth of the claims.

The Federal Circuit has clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The

court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of

sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 11-15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Batard et al (US Patent 6376753, published April 23, 2002).

The claims are drawn to any gene encoding any protein that catalyzes biosynthesis of piperitol or sesamin wherein the protein has any number of amino acid substitutions, deletions, or additions to SEQ ID NO:1 as well as a recombinant expression vector and transformant comprising said gene and methods of producing a plant and a protein comprising producing a plant comprising said gene. In claim 5, it is recited "a gene including a base sequence selected from a group consisting of SEQ ID NOS: 2, 65 and 79 as an open reading frame region". Given the broadest reasonable interpretation of the claim, "a base sequence" may comprise as little as 2 nucleotides of

SEQ ID NO:2 and therefore would inherently encompass a multitude of sequences. It is suggested that if Applicant intended to limit the claims to a gene comprising SEQ ID NO:2, that the claim be amended accordingly. Care must be taken to avoid introducing New Matter into the claim.

Batard et al teach gene encoding a polypeptide which is a p450 protein (see claim 1), a vector comprising the gene (see claims 3-4) a transformed plant comprising said vector (see claims 7-9), wherein the sequence inherently would have a number of insertions, deletions and additions relative to SEQ ID NO:1, and methods for producing transgenic plants (see 1st paragraph under Field of Invention) and methods for producing the protein (see paragraphs 15-17 of the specification, for example), wherein the plant is grown and the gene overexpressed. Because the specification does not give any identifying characteristics of proteins that catalyze piperitol or sesamin other than to use p450 super family genes to search for said genes, a p450 gene is considered to catalyze biosynthesis of piperitol or sesamin absent evidence to the contrary and therefore an overexpression also inherently produces at least one piperitol or sesamin wherein the method steps are anticipated.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bevan et al (1999 UniProt TO4730, reference number Z15382).

The claims are drawn to any gene encoding any protein that catalyzes biosynthesis of piperitol or sesamin wherein the protein has any number of amino acid substitutions, deletions, or additions to SEQ ID NO:1 wherein the amino acid sequence is at least 50% homologous to an amino acid sequence from SEQ ID NO:1.

Bevan et al teach a gene encoding a p450 cytochrome polypeptide wherein the polypeptide sequence is 51.9% identical to the full-length of SEQ ID NO:1 wherein absent evidence to the contrary, the p450 cytochrome polypeptide inherently catalyzes biosynthesis of piperitol or sesamin (see attached sequence alignment).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brent Page/
Examiner, Art Unit 1638